CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Comments CDPH HSCR Advisory Committee for November 30, 2010 Meeting

Introduction:

CIRM has reviewed the *California Department of Public Health Guidelines for Human Stem Cell Research* in relation to the current *CIRM Medical and Ethical Standards Regulations*. The purpose of this review was (1) to highlight recent substantive changes to the CIRM regulation and describe policy differences that may be of interest to the HSCR Advisory Committee and (2) to offer additional comments to the HSCR Advisory Committee.

(1) Recent Amendments to the CIRM Regulations & Policy Differences

- 100080(a)(2)(B): CIRM regulations amended to include the use of all embryos that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose. Amendment serves to align CIRM with CDPH and NIH Guidelines.

- 100070(c): CIRM regulations amended to require SCRO committees to be notified of research involving identifiable somatic cells or in vitro research with de-identified somatic cells with the intent of deriving a pluripotent cell line (human subjects research). There is no such notification requirement in the state guidelines. The CDPH advisory committee believes the SCRO committee should be primarily focused derivation of cells from human embryos and research involving the use of pluripotent cells in humans and animals.[1] This more limited scope is consistent with the charge of the state advisory committee. The expanded notification requirements in the MES regulations are appropriate given CIRM is a funding agency actively managing research awards.

- 100090(a)(1) & (2): Note differences in consent requirements tied to effective date of regulations. Compare to language in section 7.

- ICOC to consider designation of hESC lines derived under the Australian Research Involving Human Embryos Act as acceptably derived for CIRM-funded research.

[1] See http://www.cdph.ca.gov/services/boards/HSCR/Documents/MO-HSCR-May21Transcript-09-2009.pdf

(2) Additional Comments to HSCR Advisory Committee

- Covered research / covered cells: The definition of "covered research" effectively encompasses activities involving hESCs. SCRO review requirements encompass a broader range of activities. Including:
  - Gamete research
  - Embryo research
  - Clinical trials
  - Introduction of human pluripotent or pluripotent-derived cells to non-human animals

  The differences in scope create some confusion among researchers. The HSCR may want to consider how the guidelines may be modified to resolve certain ambiguities resulting from this difference in scope.